Statutory Approvals Committee – minutes

Centre 0037 (Glasgow Royal Infirmary)
Special Directions application to export embryos to South Africa for use in surrogacy treatment

Thursday, 31 January 2018

Church House, Dean's Yard, Westminster, London. SW1P 3NZ

Committee members	Margaret Gilmore (Chair) Bobbie Farsides (Deputy Chair) Anne Lampe Ruth Wilde Rachel Cutting Emma Cave	
Members of the Executive	Dee Knoyle Bernice Ash Paula Robinson Sandrine Oakes Nicola Lawrence	Committee Secretary Committee Secretary (Observer) Head of Planning and Governance (Observer) Inspector (Observer for Induction) Inspector (Observer for Induction)
External adviser		
Legal Adviser	Tom Rider	Field Fisher LLP
Observers		

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The committee had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members
- General Directions 0001 (2015)
- General Directions 0006 (2018)
- General Directions 0013 (2018)
- HFEA Standing Orders (2018)
- Special Directions Decision Tree (2018)

The following papers were considered by the committee:

- Executive summary
- Special Directions Application Form
- Further Information Form
- Letter from the proposed receiving centre confirming acceptance of embryos

1. Background

1.1. The Person Responsible (PR) at Glasgow Royal Infirmary, centre 0037 has applied for Special Directions to export 3 embryos to Drs Aevitas Clinic Pty Ltd, located in South Africa for use in surrogacy treatment.

2. Consideration of application

Application

2.1. The committee noted that a suitably completed application has been submitted on the correct form.

Human Fertilisation and Embryology Act 1990 (as amended) Section 24

2.2. The committee noted that section 24(4) of the HFEA Act 1990 (as amended) permits the Authority to issue directions to allow the import and export of gametes and embryos for countries outside of the United Kingdom. The committee further noted that, in relation to the import and export of gametes and embryos outside of the European Economic Area and Gibraltar, transactions can be permitted without the need for directions if the conditions outlined in General Directions 0006 are satisfied.

General Directions 0006, Schedule 4, Part 1 (b) and (c)

2.3. The committee noted that the centre is unable to export the eggs under General Direction 0006 because the requirements of Schedule 4, part 1 (b) and (c) cannot be met.

Schedule 4 of the General Direction provide as follows:

Part 1

b) The receiving centre has a quality management system (QMS) in place which has been certified by an internationally recognised body.

c) The receiving centre has a traceability system in place which ensures that all gametes and embryos are traceable from procurement of gametes to patient treatment and vice versa. The centre's traceability procedures should also encompass all materials or equipment that could have an impact on the quality or safety of the gametes and embryos.

Quality Management System (QMS) – not certified by internationally recognised body

2.4. The centre is unable to comply with Schedule 4, part 1 (b) of the General Direction 0006 for the reasons outlined below.

2.5. The proposed receiving centre does not have a quality management system that is certified by an internationally recognised body. However, the Executive has some assurance that an effective quality management system is in place. The committee also noted that the proposed receiving centre is certified to the national standards in South Africa.

Traceability – Standard Operating Procedures - not certified by an internationally recognised body

2.6. The centre is unable to comply with Schedule 4, part 1 (c) of the General Direction 0006 for the reasons outlined below.

2.7. Whilst Standard Operating Procedures (SOPs) are in place at the proposed receiving centre in relation to the data collection platform, sperm preparation, oocyte retrieval and sperm procurement, these are not certified by an internationally recognised body.

2.8. A request was made for traceability SOPs/audits that demonstrated that all gametes/embryos/ consumables and media used/embryologists performing each task/equipment used are all traceable for a patient's treatment. The proposed receiving clinic was unable to provide this, however copies of SOPs that contain elements of traceability were submitted.

2.9. An SOP for the clinic's computer filing system was requested. The clinic was unable to provide this, however sent screenshots detailing some of the forms used.

3. Decision

3.1. The committee had regard to:

- The Human Fertilisation and Embryology Act 1990 (as amended)
- Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 ('the 2009 Regulations')
- HFEA General Directions 0006
- The Human Rights Act 1998:
- Article 8 - respect for private and family life
- Article 12 - right to marry and found a family

3.2. The committee had regard to the Authority's statutory duty to promote, in relation to activities governed by the Act, compliance with requirements imposed by or under the Act.

3.3. The committee noted that Special Directions have been applied for because Schedule 4, Part 1 (b) and (c) of the General Direction could not be met.

3.4. In considering the application, the committee had regard to the principles (tests) derived from the decision of the Court of Appeal in the Blood case and from rights arising under the Human Rights Act 1998. The committee considered whether a refusal to make Special Directions would be an interference with the patients' rights under Articles 8 and/or 12 of the European Convention on Human Rights and whether such interference would be justified and proportionate. The committee agreed that refusal may amount to interference in this case.

3.5. The patient couple wish to use their embryos for treatment using a surrogate at Drs Aevitas Clinic Pty Ltd located in South Africa, to produce a child which they will parent. The couple have chosen South Africa for the treatment as this is the country of residence of the proposed surrogate. These embryos were created using the patient couple's own gametes and are essential to the treatment as they wish to have a child which is genetically linked to them.

3.6. Taking all of these factors into account, including the age of the patient and medical history of the patient's partner, the committee agreed that this case involved a highly exceptional set of circumstances and agreed to issue Special Directions to allow the export of the patient couple's 3 embryos to Drs Aevitas Clinic Pty Ltd, South Africa.

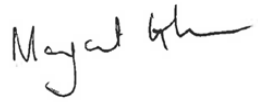
3.7. The committee considered that granting Special Directions for this application would not set an undesirable precedent which would undermine the imperative requirements identified.

3.8. The committee agreed that the PR should be mindful of the complex issues of legal parenthood in surrogacy cases when bringing the child back to the UK and provide the patient couple with all the relevant information in relation to this matter.

4. Decision

4.1. I confirm this is a true and accurate record of the meeting.

Signature



Name

Margaret Gilmore

Date

25 February 2019